

REMARKS/ARGUMENTS

Claims 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-48, 69, 71, 73, 76, 79-85, 97-100, and 107 were examined and rejected. The claims have been amended and canceled as noted above. Reexamination and reconsideration of the claims, in view of the above amendments and the following remarks, are respectfully requested.

The objections and rejections of the claims as failing to comply with the enablement requirement and as being indefinite have been overcome as follows.

Claim 1 has been amended to state that the balloon inflation lumen is on the shaft of the first balloon structure. Applicants apologize for the mistake made in the last amendment. Claim 2 has been amended to clarify that the axial groove is on the shaft, not on the sleeve passage.

With these amendments, Applicants believe that the rejections for enablement and indefiniteness have been overcome.

Turning now to the obviousness rejections, Applicants have amended claims 1 and 2 in a manner which clearly distinguishes the teachings of Kraus even when combined with McKeever. Such amendments are made without prejudice to refiling claims of a different or broader scope in subsequent applications.

Claim 1, as now amended, sets forth an intravascular balloon catheter comprising both a catheter body and a first balloon structure. The catheter body has at least a guidewire lumen which permits introduction into the vasculature in a conventional manner. The first balloon structure includes a shaft and a balloon sleeve. The shaft includes a balloon inflation lumen and has sufficient column strength to advance the balloon structure over the catheter body. The balloon sleeve is disposed at a distal end of the shaft and carries an inflatable balloon thereon. The sleeve further has a sleeve passage therethrough which is slidably receivable over the catheter body, thus allowing it to be advanced by the shaft.

Claim 1 thus sets forth that the axial groove is present along at least a portion of the shaft to removably receive at least a portion of the catheter body. As described in more detail

below, neither Kraus nor McKeever describe such a structure, particularly the inclusion of the axial groove.

Claim 2 has been amended similarly to claim 1. Claim 2 now sets forth an intravascular balloon catheter comprising a catheter body and a first balloon structure. The catheter body includes a guidewire lumen, and a first balloon structure includes a shaft and a balloon sleeve, where the balloon sleeve is disposed at the distal end of the shaft. The shaft has sufficient column strength to permit advancement of the balloon structure over the catheter body, and the sleeve passage slidably receives the catheter body. As with claim 1, claim 2 has been amended to clarify that the axial groove is present along at least a portion of the shaft for receiving the catheter body.

While the balloon catheter structure of Kraus is similar to that of the present invention in certain respects, it is very different in other respects. In particular, the balloon structure of Kraus (Fig. 6) includes a balloon 51 present on an internal tube 56, where the balloon and tube are not connected to a shaft as required by both claims 1 and 2 herein. Instead, the balloon and tube are connected to an inflation lumen 52 which is not taught to have any column strength. Advancement of the balloon is achieved only by using the bumper 53 on the end of pushrod 54.

As presently amended, both claims 1 and 2 now require that the shaft be fixed to the balloon structure and have "sufficient column strength to advance the balloon structure over the catheter body."

Claims 1 and 2 have also been amended to clarify that the axial groove is present on the shaft to removably receive the catheter body. Kraus neither teaches nor suggests that a groove be formed in the inflation lumen 52 (which is the only element fixed to the balloon 51).

The Examiner argues that the guidewire 29 of Kraus is somehow equivalent to the catheter body of the present invention and that the pushrod 34 would be analogous to the shaft of the present invention. This argument cannot be sustained, particularly with respect to the amended claims. Claims 1 and 2 both require that the shaft be fixably connected to the balloon sleeve which carries the balloon. Kraus, in contrast, requires that the balloon be separate from the pushrod in order to permit balloon exchange as described in the patent.

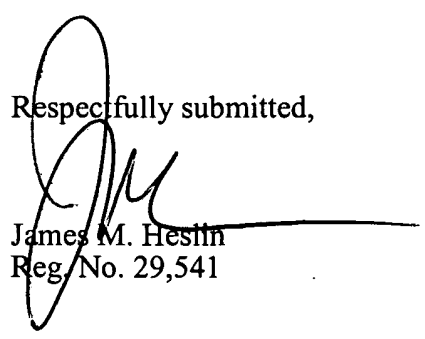
The Examiner's reliance on McKeever does not cure the deficiencies of Kraus. McKeever describes an intra-aortic balloon pump which can be delivered coaxially or adjacently over a guide catheter, where the guide catheter provides for introduction of angioplasty or other interventional catheters. Figs. 4-7, relied on by the Examiner, specifically teach that the guide catheter 52 and balloon pump catheter 51 remain separate over their entire lengths except for a coupling structure at its distal end, with two different embodiments shown in Figs. 5 and 7 respectively. Thus, contrary to the Examiner's assertion, McKeever would suggest only coupling of the guidewire at the distal end of the pusher, as shown in Fig. 6 of Kraus, not providing an axial groove for receiving a separate catheter body, as required by the claims of the present invention.

CONCLUSION

In view of the above amendments and remarks, Applicants believe that all claims are now in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,


James M. Heslin
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
JMH:jis
60916789 v1